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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,555	03/01/2002	Jerald K. Rasmussen	54652US008	3817

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,555	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2/1/02</u> | 6) <input type="checkbox"/> Other: _____ |

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This application is a continuation of application 09/240,829, now patent 6,379,952.

A preliminary amendment of 3/1/02 amended the specification, canceled claims 1-11 and amended claims 12 and 13.

5 Claims examined on the merits are 12-17, which are all claims in the application.

Specification

The disclosure is objected to because of the following informalities: the abstract is not sufficiently informative of the subject matter of the specification. The following abstract is suggested ---

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Azlactone-functional supports are used to provide cell selection from a mixture such as bone marrow or peripheral blood. An azlactone-functional support is derivatized by covalently coupling to the support a biologically active substance such as selected from antibodies, lectins, proteins, antigens and avidin that binds to target cells. A mixture containing target cells is contacted with the derivatized support to bind the target cells to the biologically active substance, unbound remaining mixture is removed, and optionally bound cells are eluted to obtain a purified cell collection. The biologically active substance may indirectly bind cells through a second, intermediary biologically active substance that is bifunctional. The azlactone-functional support is provided by incorporating an azlactone moiety into a base polymer support that has been selected by prescreening base polymer supports with a cell

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mixture to identify a base polymer support having minimal nonspecific binding of cells in the mixture. ---.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5 The following is a quotation of the first paragraph of 35 U.S.C.
112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 Requiring the support to have surface azlactone moieties as in line 2 of claim 13 as being a species of azlactone-functional support required in claim 12 is not described in the specification. The support of claim 12 would have to contain surface azlactone moieties, or a biologically active substance would not covalently bind to the support. It is suggested that claim 13 be amended by canceling "the
25 azlactone-functional support is a support having a surface comprising azlactone moieties,".

 In line 4, "solid plastic particle" is not supported in the specification. Original claim 13 discloses a "solid plastic article",

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and it is not readily apparent where the specification recites "solid plastic particle".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

5 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In line 1 of claim 12, "interacted support" is uncertain as to how "interacted" defines the support. It is suggested that "An interacted support" be replaced with --- A support containing bound whole cells ---.

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In line 2 of claim 12, "azlactone-functional support" is unclear as to whether the support reacts with an azlactone moiety or contains an azlactone moiety. It is suggested this line be amended by after "support" inserting --- comprising one or more base polymer supports containing an azlactone moiety ---. With this change, line 5 should be amended by canceling "azlactone-functional support comprises".

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In line 4 of claim 12 "interacting" is relative and subjective as to phenomena that constitutes interacting. It is suggested that "interacting with" be replaced with --- bound to ---.

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Claim 13 is confusing by requiring the support to have surface azlactone moieties since this would have to inherent in claim 12 for binding of the biologically active substance to occur.

In line 2 of claim 13, "comprising" should be replaced with ---
5 is in the form of --- since reciting "comprising" makes unclear as to the relationship of the materials recited to the support.

In line 1 of claim 16, there is not clear antecedent basis for "the solid plastic article".

Claim Rejections - 35 USC § 103

10 Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al (5,993,935) in view of Rothschild et al (6,057,096) and Berenson et al (5,215,927).

The claims are drawn to an azlactone-functional support containing a covalently bound biologically active substance and whole
15 cells bound to the substance, and wherein the support contains a base polymer that has been prescreened and identified as exhibiting minimal nonspecific binding of whole cells.

Rasmussen et al disclose (col 9, lines 15-62) an azlactone-functional support (col 5, lines 20-67) containing a covalently bound
20 ligand for use as an adsorbent to carry out affinity separations (col 9, line 59).

Rothschild et al disclose coupling cell adhesion molecules to a support to carry out separation of target cells (col 7, lines 36-61, and col 43, lines 23-57).

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Berenson et al disclose using immobilized avidin to isolate target cells that have been reacted with a biotinylated antibody to form a biotinylated cell complex (col 3, lines 32-68).

It would have been obvious to use as the ligand of Rasmussen et al a ligand that binds cells and use the bound ligand to separate target cells as suggested by Rothschild et al and Berenson et al isolating target cells by using an immobilized ligand that binds the target cells or that binds a complex of the target cells containing a component that binds to the ligand. A base polymer used by Rasmussen et al can inherently have minimal nonspecific binding for certain types of cells. Defining the base polymer in terms of screening for minimal nonspecific binding does not make the base polymer different. Furthermore, it would have been obvious to select from the polymers of Rasmussen et al a polymer that has minimal nonspecific binding since a polymer that binds a significant number of cells other than the desired cells will have obviously been expected not to provide target cells of desired purity.

Response to Arguments

Applicant's arguments filed 3/1/02 in the preliminary amendment have been fully considered but they are not persuasive.

The argument that the claims require a species of polymer that has been prescreened for minimal nonspecific cell binding is unpersuasive since the polymer of Rasmussen et al inherently has minimal nonspecific binding for certain types of cells. A polymer obtained by prescreening as claimed does not have to be different.

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Even if the *Polymer Handbook* supplied by applicants discloses a large number of different polymers, this does not preclude the polymer of Rasmussen et al from having minimal binding for certain types of cells. The nonspecific binding of the claims can be for any cells, and the prescreening of the claims can result in the same polymer as used by Rasmussen et al. The present claims are drawn to a product rather than a process, and obtaining the polymer by prescreening does not preclude the polymer from being the same as used by Rasmussen et al. As to obviousness of prescreening, there is clear motivation since nonspecific binding of cells is obviously going to result in cells bound being impure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,952 B1. Although the conflicting claims

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are not identical, they are not patentably distinct from each other because the method of the claims of the patent require producing a support containing bound cells as presently claimed.

Any inquiry concerning this communication or earlier
5 communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-
10 4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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David M. Naff
Primary Examiner
Art Unit 1651

20 DMN
12/12/03